

CONTROLLED SUBSTANCE GUIDELINES

FOR

MISSOURI PHARMACIES



BUREAU OF NARCOTICS & DANGEROUS DRUGS

MISSOURI DEPARTMENT OF HEALTH & SENIOR SERVICES

The Bureau of Narcotics and Dangerous Drugs has published this guideline as a quick reference source for Missouri pharmacies. This guideline is a compilation of the most commonly asked questions and issues arising daily. Unlike other medical practitioners with controlled substance registrations, the pharmacies focus their practice on the distribution and dispensing of controlled substances and routinely work with all of the record keeping requirements affiliated with the handling of controlled substances. For this reason, the bureau only touches briefly upon the routine areas of receipt records and inventories and focuses more on prescription requirements, dispensing, special circumstances for long-term care, hospice and other special situations.

This guideline is designed chronologically in the order of obtaining a registration, purchasing, record keeping, dispensing, and security issues.

As a licensed professional and controlled substance registrant, it is your responsibility to know and comply with state and federal controlled substance laws and also to insure that subordinates acting under your authority are complying with the law.

To review all of the controlled substance laws and regulations for the state of Missouri, and also obtain additional educational handouts and forms, please visit the Bureau's website at <https://health.mo.gov/safety/bnodd>.

Additional websites for educational information are as follows:

Drug Enforcement Administration.....www.deadiversion.usdoj.gov

Missouri Board of Pharmacy.....www.pr.mo.gov/pharmacists.asp

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REGISTRATIONS

Who is required to have a registration?

All persons and businesses in Missouri who want to conduct any activities with controlled substances, including purchasing, stocking, ordering, prescribing and administering, must first obtain a state controlled substances registration. No person in Missouri may conduct any controlled substance activity without a state registration. A person obtains their professional license first and then the state controlled substance registration is obtained second. The federal DEA registration is obtained last.

What about federal DEA registrations?

After a professional license and state controlled drug registration are issued, then a federal DEA registration must be obtained. The federal registration may be applied for at www.dea diversion.usdoj.gov

How do I apply and what is the process?

A person may apply for a new state controlled substances registration at any time. Once a professional license has been issued, the pharmacy may apply for and obtain a Missouri Controlled Substances Registration and then a federal DEA registration. You must apply online at the BNDD website <https://health.mo.gov/safety/bndd>. Applications are submitted electronically online where fees can be paid with a credit card.

To save time, you may apply for your state license; state controlled drug registration and federal DEA registration at the same time. When filling out the state controlled substances application, write the word, “pending,” in the line for your state license number. When the state board issues your license, you may contact the Bureau with your new license number so that the application can be processed. When filling out the federal DEA application, it will ask for your state controlled substances registration number. You may also enter the word, “pending,” in this line. Once our Bureau has issued a new Missouri state number, you can contact the DEA with that final information.

It typically takes 1 to 15 workdays for BNDD to process the application. The bureau has a goal to issue registrations on completed applications within 15 days. Fluctuating workloads may occasionally cause the process to take longer.

State registrations issued in Missouri only

A registration may only be issued at a Missouri practice location where controlled substance activities take place and patient care occurs. A registration is required at each place where controlled substances are stocked, distributed or dispensed in Missouri. The bureau does not require out of state pharmacies or distributors to obtain a Missouri registration in order to ship into Missouri, as long as they are only shipping and they do not have a storage facility in Missouri.

Notifying the regulatory authorities if you change practice locations.

It is important that state and federal regulatory agencies have the ability to contact you. It is required that you notify agencies when you change practice locations. If you change practice locations, you have 30 days to notify our Bureau of your new location or your controlled substance registration automatically terminates.

What can cause a registration to close or automatically terminate?

The following circumstances can cause a registration to terminate:

1. A registration closes on the date of expiration printed on the certificate. There are no extensions or waivers issued under the law. A new registration must be obtained to conduct controlled drug activities.
2. When a pharmacy goes out of businesses, ceases legal existence or does not have their professional license or pharmacy permit.
3. If and when a business changes ownership. Registrations cannot be transferred to another person. The new owners must have their own registration. When there is a change of ownership, the new owner may operate under the registration of the seller during a 30-day grace period. By the 31st day, the new owners must have obtained their own.
5. If and when the person discontinues business or changes practice location. There is a 30-day grace period to notify the BNDD within 30 days of the effective date of the change.
6. A registration may be terminated at the request of the registrant.

How do I make changes to my existing registration?

Changes to an existing registration may be completed at the BNDD website or by mailing or faxing a written request to the Bureau. The Bureau will change names, addresses, and adjust drug schedules for no additional fee.

Will I automatically get a renewal notice?

Although not required by law, as a courtesy the BNDD sends an email to each registrant, 60 days before the expiration date of their current registration. The BNDD emails the reminder to the address the Bureau has on file from the registrant's application. Please insure email addresses are up to date.

Registration certificates should be kept readily retrievable.

Your federal DEA controlled substance registration must be maintained at your registered practice location and must be readily retrievable upon inspection.

BNDD Registration Certificates

The BNDD will no longer be mailing printed certificates. Registrants may verify and print their registration data from the website at <https://health.mo.gov/safety/bndd>.

LTCFs Have Their Own Registrations

Retail pharmacies do not need to obtain registrations at LTCFs to transfer drug stock to LTCFs. In Missouri LTCFs have their own drug registrations. LTCFs are separately registered and are responsible for controlled substances that enter their facilities. There is much more detailed information that follows in the section addressing LTCFs and pharmacy relationships.

How much can a pharmacy transfer?

A pharmacy can transfer up to 5% of their stock. Once meeting the 5% threshold, they must obtain a license and registration as a distributor.

REQUIRED RECORD KEEPING

Each and every time controlled substances change hands or are used, documentation must be generated and maintained. There should be a paper trail to show the path of a controlled substance dosage unit from the day it was manufactured, through the distributor, to the pharmacy, to a practitioner and then ultimately to the end user.

State and federal controlled substance laws require all controlled substance records to be maintained for a period of two years. These records must be maintained at the registered practice location and must be readily retrievable and open to inspection and copying by the BNDD. Your state licensing board may require you to keep patient records for a longer period of time. Pursuant to Section 195.375.5, RSMo all controlled substance records are open for inspection to the BNDD, DEA and local, state and federal law enforcement agencies enforcing drug laws.

Receipt records

A registrant is required to maintain a file of receipt records that documents the receipt of all controlled substances received. The receipt records for Schedule III—V drugs should be in a separate file from the DEA Form 222 Official Order Forms used for Schedule II drugs. Registrants must maintain the following information for all controlled substances received:

1. Date of receipt;
2. Drug name
3. Dosage form
4. Drug strength
5. Quantity received
6. Name, address and DEA number of the supplier
7. Name, address and DEA number of the recipient (*No DEA# for LTCFs*)
8. Name or initials of employees verifying receipt of the drugs

These receipt records may be kept in a handwritten or typed log or may be maintained electronically. The third copies of all DEA Form 222 Order Forms must be signed and dated to verify receipt of the Schedule II drugs.

If a practitioner chooses to use a supplier's invoice, billing record, or packing document as a record of receipt, it that practitioner's responsibility to review the document to make sure that the required information is documented on the receipt record.

Initial inventory

On the very first date that you receive and engage in the stocking and receipt of controlled substances, you must perform an initial inventory of the controlled substances on hand. There are inventory forms on the Bureau's website that you may use. The following information must be documented on an inventory:

1. Date
2. Documentation of whether the inventory was taken at Opening of business (OOB) or Closing of business (COB) or time of inventory if practice location is open 24 hours a day.
3. Drug name
4. Drug strength
5. Dosage form
6. Quantity of dosage units on hand

The initial inventory of Schedule II drugs must be maintained on a separate form and document than the initial inventory of Schedule III—V drugs. All inventories must be on paper and not electronic.

Do not perform an inventory that combines Schedule II drug counts with drugs in Schedule III—V and do not include any non-controlled drugs on these inventory documents.

Annual inventory

After an initial inventory has been completed on the day you first started stocking controlled substances, the registrant shall take a new inventory of all controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date.

The same information must be maintained in the annual inventory as listed above in the requirements for the first initial inventory. All of the six areas of information listed above must be documented. Schedule II drugs should be documented on a separate form. Do not combine non-controlled drugs on the annual controlled substance inventory.

In order to save time and work, you may decide to coincide your annual inventory date with the date of your business inventory at the end of the year for tax purposes.

Counting the controlled substances

All controlled substance dosage units are to be included regardless of whether they are in stock bottles, set aside for destruction, outdated, or samples. When counting controlled substances in Schedules III—V, the practitioner may open a bottle and estimate the number, if the stock bottle is labeled to contain less than 1,000 dosage units. If the stock bottle is labeled to contain 1,000 units or more, then an individual hand count must be performed to provide an exact count. Bottles & containers also get listed.

When Schedule II controlled substances are counted, they must be hand-counted every time. No estimating is allowed for Schedule II controlled substances.

If you stock all schedules, you must have two annual inventory documents; one for Schedule II and one for Schedules III—V. You must file these documents and maintain them for two years.

Perpetual logs

Pharmacies may choose to maintain an ongoing log of all drugs dispensed. This provides an ongoing count every day of what they have used and what they still have on hand. Perpetual logs are useful and encouraged, however maintaining a daily perpetual log does not replace the requirement to have a specific annual inventory document. Annual inventories must always be separate documents that stand-alone and are maintained separately.

Dispensing records

Pharmacies are required to maintain records of all controlled substances dispensed.

1. Date of dispensing
2. Patient name/owner if animal
3. Patient address/owner if animal
4. Drug name
5. Drug strength
6. Dosage form
7. Quantity
8. Name or initials of employee performing the dispensing

Required packaging and labeling when dispensing controlled substances

When a practitioner dispenses controlled substances to a patient such that the patient leaves the practice site with controlled substances for future use, the practitioner must be sure that state and federal laws are being followed regarding required labeling and packaging.

Packaging: Controlled substances must be dispensed in child-proof containers, in accordance with the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471-1476. Controlled substance samples that are provided in approved pre-packaged containers are approved by the FDA for dispensing and practitioner are not required to re-package controlled substance samples. Controlled substances should not be dispensed in envelopes, plastic bags or other unapproved containers.

Labeling: All controlled substances dispensed must have proper labeling applied by the dispensing practitioner. Practitioners must obey the same labeling laws as do pharmacies. The practitioner must apply required labels and stickers to all childproof containers used for dispensing, including the pre-packaged containers. Required labeling includes:

1. Date of dispensing
2. Name and address of dispensing pharmacy
3. Patient's name
4. Drug name, drug strength, dosage form and quantity
5. Directions for administration

Warning labels: All controlled substances dispensed must bear a warning sticker that informs the owner that it is illegal to transfer controlled substances to anyone other than the patient for whom it was dispensed. These stickers are available through drug companies or pharmacies.

Disposal of unwanted controlled substances

Controlled substances are wasted or destroyed for two reasons; they are outdated, expired or unwanted, or secondly they have been contaminated by patient contact.

Only controlled substances contaminated by patient contact may be destroyed onsite by a practitioner.

Outdated/expired controlled substances may not be destroyed on site by a practitioner without prior approval from the United States Drug Enforcement Administration.

When a drug has been contaminated by patient contact it should be destroyed beyond reclamation by two people and the required documentation should be completed as review previously in this guideline.

You may obtain a list of reverse distributors from the Bureau's website and they will inventory the drugs you wish to have destroyed and they will remove and destroy the drugs for you. They will provide you with a receipt to show that you transferred the controlled drugs to them. This document must be maintained for at least two years to document this activity.

Registrants may contact their local DEA field office and ask permission to destroy their own drugs on site and document the destruction on a DEA Form 41.

Disposal of Patients' Unwanted Drugs—Collection Boxes:

Registrants may participate in the collection and return of patient medication in accordance with federal DEA regulations. Collection boxes may be placed in pharmacies, hospitals, long-term care facilities, and locations registered as narcotic treatment programs. Registrants must notify the BNDD in writing of their desire to have a collection box. The BNDD will respond in writing to authorize a collection box. No special application or fee is required. The registrant may then contact the DEA to get authorization and become a collector. Missouri regulations require all registrants to follow the existing federal DEA laws pertaining to collecting, security and record keeping.

Transferring of controlled substances among registrants

Controlled substances are routinely transferred among registrants, such as when you purchase drugs from a distributor. If you transfer controlled substances to a reverse distributor or sell controlled substances to another practitioner, records of transfer must be maintained. The Bureau's website provides a pre-printed Transfer of Controlled Substances Form as an example. If you use that form and complete it completely and accurately, your records of transfer should comply with the law.

All transfers of Schedule II drugs must be documented on a DEA Form 222 Official Order Form.

Schedule III—V drugs may be transferred on the form provided by the Bureau or another form designed by the practitioner, as long as all required documentation is present. The document must include:

1. Name, address and DEA number of the supplier
2. Name, address and DEA number of the receiver (*No DEA# for LTCFs*)
3. Date of the transfer
4. Name, strength, dosage form and quantity of the drug(s) transferred.

If both parties have a copy of this document, it can serve as a transfer document for the supplier and also a receipt record for the receiver.

Typically, execution of DEA Form 222 Official Order Forms should only be performed by the registered practitioner. The registered practitioner may delegate this authority and authorize another employee to execute these forms, if the registrant and employee execute a power of attorney form as authorized by federal regulation.

Please remember !! When you provide controlled substances to a medical practitioner for administration and dispensing in their offices, a pharmacy should transfer these drugs to the other registrant. Never allow a practitioner to write a prescription for office stock. Prescriptions are for patients only and prescriptions are never to be used by practitioners to obtain supplies of drugs for office use.

Pharmacies have 3-part filing system for paper prescriptions:

Prescriptions arriving in the pharmacy are filed in a 3-part filing system.

1. Non-controlled or legend drugs in one section;
2. Schedule II controlled substance prescriptions filed in one section;
3. Schedule III—V controlled substance prescriptions filed in one section.

Controlled substance prescriptions arriving electronically are not to be converted to paper for filing. The DEA rule states that what starts electronic must stay electronic and an electronic prescription cannot go to a pharmacy's fax machine. That is because a faxed prescription requires a manual signature.

All rules apply to all pharmacies

The state and federal controlled substance laws apply to all pharmacies. There are not separate rules or exceptions for a retail pharmacy compared to a long-term care pharmacy.

Prescriptions with multiple drugs: Are they legal? How are they filed?

It is common to see one prescription form with multiple drugs prescribed on one form. If all of the required elements are present the prescriptions are legal and may be dispensed. The pharmacy can assign a different prescription number to each drug. The pharmacy may need to copy the prescription so that the scheduled drugs can be filed separately from the non-controlled drugs.

Database reporting for Schedule 5 pseudoephedrine products

As of September 28, 2010, a rule was promulgated that requires all pharmacies that dispense Schedule 5 methamphetamine precursor products to report those sales to a database. The database is the Missouri National Precursor Log Exchange (MONPLEx). If any of these drug products are sold without a prescription, it must be reported to the database. These schedule 5 products dispensed pursuant to a prescription are exempt from being reported to the database.

STORAGE OF CONTROLLED SUBSTANCES

Pharmacies must keep their Schedule II controlled substances locked in a safe or cabinet at all times. Schedule III—V controlled substances do not have to be locked in a safe or cabinet, if these drugs are dispersed among the other non-controlled drugs within the pharmacy. If Schedule III—V drugs are not dispersed among the other non-controlled drugs, then they must be locked and secured.

If there is a large volume or stock of Schedule III—V drugs held separately in another storage area, they must be secured as required by law.

Pharmacies are authorized to secure their controlled substances in a locked walk-in vault that is secured from other areas of the pharmacy.

Pursuant to state and federal rules, the level of security must be commensurate with the quantities of controlled substances handled.

PRESCRIPTION & DISPENSING ISSUES

Documentation Required on Written Prescriptions

State and federal law requires that a prescription must have all of the information required documented on the face of the prescription in order for the prescription to be legal. Federal law states that both the prescriber and the pharmacy have a corresponding liability to make sure the information is documented. Both the prescriber and the pharmacy are liable. The following information is required for controlled substance purposes:

- The date the prescription was signed and issued;
- Patient's name and address;
- Name, address and DEA number of the prescriber;
- Drug name, strength, dosage form, quantity to be dispensed;
- Directions for administration or use;
- Signature of the prescriber- original ink if patient presents prescription at the pharmacy.

- If the prescription is for greater than a 30-day supply of a Schedule II drug, the prescriber must write the medical reason on the prescription. A diagnosis code number is not acceptable.
- If the practitioner does not want the prescription filled until a certain date the prescriber may write “Do not fill until _____” at the bottom of the prescription.

A prescription is what the practitioner writes on the front face of the prescription form.

The sticker and information the pharmacy places on the back of the form is a pharmacy dispensing record.

Prescriptions Transmitted Verbally by Telephone

Prescriptions for Schedules III—V may be telephoned to a pharmacy. All of the information listed above is still required. The pharmacist must reduce it in writing and document the name of the person making the call and pharmacy employee receiving the call. Schedule II prescriptions may only be phoned in for emergencies where no other medical care is available. The prescriber must provide the pharmacy with an original prescription within 7 days. If no original prescription is presented as required, the pharmacy is mandated to report the prescriber to BNDD by law.

Faxing Controlled Substance Prescriptions

A prescription may be transmitted by fax machine, however the document faxed must be a facsimile of a completely documented prescription that contains all of the required information. The prescription should be prepared with all of the required information. The practitioner must physically and manually sign it as required and then it may be faxed only after the prescriber has signed. The practitioner’s signature cannot not be printed by another person and it may not be stamped and it may not say, “signature on file.” A digitally scanned in electronic signature cannot be faxed. If the prescription is transmitted from a doctor’s computer, via electronic prescribing, it may only be sent to a pharmacy’s computer and cannot be sent to a fax machine. The DEA federal rule states that what starts electronic must stay electronic.

The majority of all faxed controlled substance prescriptions are for Schedules III, IV and V.

There are limitations for Schedule II prescriptions when sent by fax:

- Although a prescriber may fax a Schedule II prescription so the pharmacy can get it ready, the pharmacy cannot dispense it until the patient presents the original prescription.
- The pharmacy may dispense a Schedule II prescription based solely on the faxed prescription under three conditions:
 1. The patient is in a long-term care facility and prescription documents that fact;
 2. The patient is in a hospice program and the prescription documents that fact;
 3. The prescription is for a narcotic preparation to be administered by infusion, meaning parenteral, intravenous, intramuscular, subcutaneous or intra-spinal.

What Can a Pharmacist Change on Prescriptions?

In the state of Missouri, pharmacies are required to follow what is informally called the NAME—NAME—NAME rule. Pharmacies cannot change the:

- NAME of the patient;
- NAME of the prescriber, or add a signature;
- NAME of the drug.

After contacting the prescriber and obtaining authorization, the pharmacy may make changes and document them on the prescription. The pharmacy should document the date and time of the call. The following changes may be made with the prescriber’s permission:

- Date written;
- Patient address;
- Prescriber’s address or phone number;

- Prescriber's DEA number;
- Directions for use;
- Quantity;
- Drug form or strength;
- Whether substitution is permitted;
- Refill information
- Verifying a faxed Schedule II drug is for a patient of an LTCF or hospice;
- Verifying a medical reason for Schedule II prescription supply that is greater than 30 days.
- Verifying an initial opiate prescription for acute pain can exceed 7 days.

Multiple Schedule II Prescriptions

A practitioner may issue multiple prescriptions for Schedule II drugs on the same date. All prescriptions should be dated at the top on the date they were signed and issued. Each prescription should have "Do not fill until ____" across the bottom. Although multiple prescriptions can be issued at once, the prescriber cannot exceed a 90-day supply of Schedule II drugs.

PRESCRIBER'S CHART OF PRESCRIBING LIMITATIONS

Prescription Characteristic	Limitation Schedule II	Limitation Schedule III and IV	Limitation Schedule V
Mode of issuing prescription	<ul style="list-style-type: none"> • Signed in original ink of written. • Verbal in an emergency by doctor only; • Faxed if injectable, To LTCF or hospice; • Electronic per DEA guidelines • Mid-levels have 5-day supply of hydrocodone only. • See next paragraph below on initial prescriptions for acute pain. 	<ul style="list-style-type: none"> • Signed in original ink if written. • Orally phoned in; or • Faxed; or • Electronic per DEA guidelines. • Mid-levels may prescribe 30 days of buprenorphine without refill for substance abuse treatment only. • See next paragraph below on initial prescriptions for acute pain. 	<ul style="list-style-type: none"> • Signed in original ink if written. • Orally phoned in; or • Faxed; or • Electronic per DEA guidelines
Refills	<ul style="list-style-type: none"> • No Refills Allowed; • Partial dispensing allowed 	Maximum of five within six months of issuing prescription	As authorized by the physician. Can be refilled PRN as prescriber allows for one year

Length of prescription validity	Six months	Six months	One year
Quantity limitations	<ul style="list-style-type: none"> • 30 days for most; • Rx for over 30 days requires medical reason; • Maximum is 90 day supply • Can write multiple & separate Rx with “Do Not fill until date” written on bottom. Can’t exceed 90 day supply 	90 days	90 days

Initial Prescriptions for Opioids in the Treatment of Acute Pain:

An initial prescription for a drug is defined in the law as when the patient has not previously received that drug during the past five (5) months. Acute pain is the pain that is expected to last only a short period of time and does not include chronic pain, cancer-related pain, hospice or other end-of-life care. When treating acute pain, and the patient has not received the opiate drug in the past 5 months, the prescriber is restricted to a 7-day supply. If needed, the prescriber can issue a new and second prescription for additional doses, after a subsequent consultation. This 7-day restriction is for the treatment of acute pain and does not apply to treatment that is not for pain such as codeine for coughing or diphenoxylate for IBS. This law applies to Missouri prescribers but not prescribers from outside of Missouri.

What Are the Exemptions and Exceptions to This 7-Day Limit?

1. Patients currently undergoing treatment for cancer;
2. Patients enrolled in hospice or receiving palliative care;
3. Patients who are residents in a licensed long-term care facility;
4. Patients receiving buprenorphine for the treatment of substance abuse;
5. The 7-day limit law does not apply to out-of-state prescribers;
6. The 7-day limit law does not apply to Missouri veterinarians;
7. If in the professional medical judgment of the practitioner, they determine that more than a 7-day supply is required to treat the patient’s acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient’s acute pain; provided that the practitioner shall document in the patient’s medical record the condition triggering necessity for more than a 7-day supply and that a non-opioid alternative was not appropriate to address the patient’s condition. **In these cases, it is extremely important that the prescriber documents similar information on the prescription so that a pharmacy would know and understand the reason for the greater supply.**

What if the Prescriber Issues a Prescription for a Prescription That Exceeds Seven Days?

A prescriber may only exceed the initial 7-day prescribing limit if there is a qualifying exception as listed in the paragraph above. The pharmacy may dispense a 7-day supply and the remainder of the prescription shall be void. The law requires a second prescriber-patient consultation before another opiate prescription is authorized.

Partial Filling of Schedule II Prescriptions

(1) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and s/he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription. *(A partial dispensing of drugs is not counted as an entire refill)*

(2) The partial filling of a prescription for controlled substances listed in Schedules II, III, IV, or V is permissible, provided that:

- (A) Partial filling may occur at the request of a patient or it may be directed by the prescriber;
- (B) Each partial dispensing is recorded in the same manner as a refilling would be;
- (C) With each partial dispensing, the pharmacy must document the date and quantity dispensed on the original prescription record or their approved electronic computer applications, provided that the electronic system meets all of the federal requirements for handling of electronic prescriptions for controlled substances, including the ability to retrieve the information pertaining to partially filled controlled substances; *(A partial dispensing does not count as an entire refill)*
- (D) The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed;
- (E) No dispensing occurs—
 - 1. For controlled substances listed in Schedule II, after sixty (60) days after the date on which the original prescription was issued; and
 - 2. For controlled substances listed in Schedules III and IV after six (6) months after the date on which the original prescription was issued;
- (F) A partial dispensing is not considered a “refill” if the patient does not receive the full authorized amount at one time; and
- (G) The prescription was written and filled in accordance with all other applicable laws and regulations.

LTCF Issues For Practitioners & Pharmacies

Residents in long-term care facilities (LTCFs) obtain their medications through prescriptions. They do not obtain their medications from “orders.” There is a legal difference between an “order” and a “prescription.”

- Orders are verbal or written instructions from the practitioner to the nursing staff to obtain some of the drugs owned by the licensed facility and immediately administer them directly to the patient. In these cases, the facility owns the drugs and they are immediately administered.
- Prescriptions are only for retail pharmacies. Pursuant to law, only a retail pharmacy may dispense a prescription. If the prescriber is issuing a prescription that goes to a pharmacy, then all of the requirements of a prescription must be met and documented on the prescription.
- Pursuant to DEA guidelines, the physicians can sign agreements to have LTCF nurses act as agents.

CAUTION: Pharmacies cannot dispense a drug unless the prescription is completely and legally written. If a practitioner does not issue a complete prescription with all the information required, this prevents the patient from obtaining their medication timely.

LTCF Emergency Kits Do Not Require a Prescription:

The residents in LTCFs obtain their daily and routine medications through prescriptions. These prescriptions are considered to be the private property of the patient and these drugs are not owned by the facility.

The BNDD considers the drugs in the emergency kit to be in the possession of the LTCF and these emergency drugs are not patient owned. The E-Kit drugs are maintained by the LTCF and they are the responsibility of the LTCF.

The DEA does not register LTCFs. According to a notice published by the DEA in the 1980s, the DEA stated they do not register and regulate LTCFs. LTCFs may stock drugs in an emergency kit without a DEA registration, as long as the LTCF is registered with a state agency such as Missouri BNDD. Since the Missouri BNDD registers LTCFs to stock drugs in an E-kit, the BNDD holds the LTCF responsible and sets forth the guidelines in State Regulation 19 CSR 1.052.

In the event of an emergency, the LTCF staff may contact the physician and obtain a verbal authorization to immediately administer from the emergency kit. This is an “order” for immediate administration from the facilities emergency stock. This is set forth in Missouri Regulation. In an emergency, once the physician has approved use of emergency drugs, the LTCF is not required to obtain additional authorization from a pharmacy. The drugs are in the possession of the LTCF and the LTCF is responsible.

There has been other information published by the DEA that they believe a LTCF should contact a pharmacy for prior permission during an emergency, however this is only a suggested guideline and it is not a federal law or regulation. The DEA is in the process of considering an entirely new type of registration for LTCFs that would allow them to obtain DEA registrations.

The bureau understands that LTCFs obtain their emergency kit stock by transfers from pharmacies. Those drugs are treated as stock of the facility. The bureau understands that after an emergency drug is used, the LTCF may send some type of documentation to the pharmacy. This serves two purposes; the document allows the pharmacy to bill a patient and also notifies the pharmacy a drug needs to be replaced.

Nurses as “agents” of the doctor:

Both the BNDD and the DEA recognize nurses in LTCFs as “agents” of the doctor. This only authorizes the LTCF nurse to telephone a controlled substance prescription to the pharmacy for a drug in Schedules III—V. The nurse cannot sign a prescription for the doctor. The prescription cannot be faxed unless the doctor signs it first. The DEA has requested that doctors and nurses sign agreements in a format the DEA has provided. Only a physician may telephone an emergency prescription for a Schedule II controlled substance.

Electronic Prescribing

The DEA has promulgated federal rules for the requirements pertaining to electronic prescribing. These rules may be viewed at the DEA website www.deadiversion.usdoj.gov. You will want to review federal rules 21 CFR 1306.08 and 21 CFR 1311.100 to 305. The Missouri regulations have been updated on July 30, 2015 to match the federal regulations. Missouri enacted a statute to mandate electronic prescribing. However, there are about 11 exceptions so pharmacies will continue to get prescriptions on paper, fax, and telephone. Prescribers may also get a waiver. The pharmacy is not liable and not required to check to see if a prescriber is compliant. The pharmacy has no liability to enforce this on prescribers.

Controlled Substance Prescriptions by Mid-Level Practitioners

The mid-level practitioners with limited controlled substance authority are Advance Practice Nurses (APRNs) and Physician Assistants (PAs) and Assistant Physicians (AP).

- They must have an agreement with a physician;
- They are given authority in Schedules 2,3,4 and 5.
- APRNs are limited to a 5-day supply of all opiates in Schedules 2 and 3. Schedule II is for hydrocodone only.
- PAs are limited to a 5-day supply for all drugs in Schedule 3, and then also a 5-day supply of hydrocodone in Schedule 2.
- All mid-levels may prescribe a 30-day supply of buprenorphine, without refill, when treatment substance abuse disorder only.

- They cannot prescribe for any relatives;
- The name of their supervising or collaborating physician must also be printed on the packaging label.

Mid-Levels from Outside Missouri: The Missouri laws place the above restrictions on Missouri mid-level practitioners practicing in Missouri. Mid-levels prescribing in other states have different authority and they may prescribe according to the laws of the state where they practice.

Treating Opiate Withdrawal & Detoxing:

The primary federal regulation to review is 21 CFR 1306.07. A practitioner may administer narcotics to a narcotic dependent person, under the following circumstances:

- 1) The provider is registered with the BNDD and DEA as a Narcotic Treatment Program (NTP);
- 2) The provider is trained and registered with DEA to treat these patients pursuant to 21 CFR 1301.28. These are the Office Based Opiate Treatment (OBOT) practitioner with an “x” after their DEA number to document they treat with Suboxone and other drugs in Schedule 3,4,5.
- 3) A practitioner may never prescribe methadone to adults for these reasons. *(There is one exception below for infants)*
- 4) A practitioner may administer but not dispense a narcotic to a patient while they are arranging for the patient to enter a treatment program. These administrations may only take place for 3 days. The DEA states that the same physician must perform the administering each day.
- 5) If a patient is admitted to a hospital and is an in-patient, the hospital is authorized to treat the entire person and all ailments until the patient is discharged.

Methadone Prescriptions For Infants With Opiate Withdrawal

Previously the state and federal laws did not allow methadone to be prescribed to treat opiate withdrawal. There is one exception and this is for the treatment of infants.

- Infants born with opiate dependency cannot stay in a hospital indefinitely;
- The previous laws only allowed a physician to administer to a patient for 3 days;
- Hospitals cannot re-admit an infant every 3 days for ongoing treatment;
- Narcotic treatment programs do not take infants;
- It was determined that infants with dependency, do not rise to the level of “criminal addiction”;
- Infants with opiate dependency can be treated in two different ways:
 - 1) Upon discharge from a hospital, the hospital pharmacy can dispense methadone;
 - 2) A physician may write a prescription for methadone to treat the infant and a retail pharmacy may dispense it. The prescription should document the patient is an infant. There should be very specific and clear dosing instructions to prevent poisoning and overdose.

In 2001, the Federal Interagency Narcotic Treatment Policy Review Board (INTPRB) decided that the use of opioids for neonatal infants and children suffering opioid withdrawal does not fall under the Narcotic Addict Treatment Act (NATA) and is not subject to the same rules and regulations affiliated with the Act. The INTPRB found that an increasing number of hospitals were requesting authorization to discharge opiate-dependent infants with small quantities of methadone for administration to the infant by a responsible individual. The INTPRB stressed to practitioners that these infants are not considered narcotic addicts. Thus, the NATA does not apply. In addition, the INTPRB emphasized that a physician treating IAS or NAS was free to write prescriptions for any opioid, including methadone, that would be appropriate to treat IAS or NAS based on clinical judgment, existing standards of practice, and the patient’s response to therapy.

Treating Narcotic Addicts in LTCFs

These procedures do not apply to prescribing for patients who have physical dependence or tolerance from legitimate medical use of narcotic drugs.

Please Verify Your Initial Requirements:

1. The facility must be licensed as a long-term care facility in the state of Missouri.
2. The facility itself must have a Missouri Controlled Substances Registration Certificate issued by the Missouri Bureau of Narcotics and Dangerous Drugs. This certificate must bear the facility's current name and address. The registration must be issued to the facility and not to a pharmacy that stocks controlled substances and provides pharmacy services.
3. Pursuant to federal regulation, if a Missouri LTCF has a Missouri Controlled Substances Registration for their emergency medications, then no federal registration is required from the United States Drug Enforcement Administration. A federal registration is required if the drug stock extends past the emergency supply and floor stock is being used.
4. The patient receiving the treatment must be admitted to the facility and must be a resident of the LTCF. This should be a situation of providing continual care. A patient cannot be admitted to a LTCF just for the sole purpose of receiving addiction, maintenance and detoxification treatment.

Immediate Care Provided by Physicians:

1. A physician or mid-level practitioner may prescribe buprenorphine to treat substance abuse disorder.
2. Although mid-level practitioners are limited to a 5-day supply of opiates, there is an exception in the law where they can prescribe a maximum of a 30-day supply of buprenorphine for substance abuse disorder only, but not for the treatment of pain.

Administering Methadone:

1. A licensed physician with state and federal controlled substance registrations may administer methadone to an addicted patient for a period not to exceed three days. The key elements are:
 - The physician must be currently licensed in Missouri;
 - The physician must have a state BNDD registration;
 - The physician must have a federal DEA registration; [21 CFR 1301.28]
 - The methadone must be administered from the physician's own registered inventory and cannot be obtained by prescription;
 - The methadone must be administered to the patient at the physician's registered location by a person authorized to administer or the it may be administered in the LTCF if the physician personally administers it.
 - This treatment is temporary and cannot exceed three days. This is considered emergency treatment and it may not be extended or renewed. [21 CFR 1306.07(b)]
2. During the three days of initial treatment, the physician and facility have these three days to enroll the patient in a licensed and registered Opioid Treatment Program.
3. The Opioid Treatment Program should be licensed through the Missouri Department of Mental Health's Division of Alcohol and Drug Abuse. The Opioid Treatment Program should have a state and federal controlled substances registration.
4. The Opioid Treatment Program can work with the physician and facility to determine the proper course of care.
5. The Opioid Treatment Program will provide the methadone to the LTCF for administration. This methadone should arrive at the facility from the Opioid Treatment Program and not a retail pharmacy.

Record Keeping and Security:

1. Controlled substances arriving at the LTCFs should be locked and secured pursuant to state and federal laws.

2. The methadone should be received, stored, administered and documented in the same manner as a controlled substance prescription from a pharmacy. The administration should be documented in the patient's chart so that records may be provided to the Opioid Treatment Program as required.

Prescriptions Go to Patients—Not to Prescribing Practitioner

When a controlled substance prescription is dispensed, it should never go to the prescriber.

- A) Pharmacies are authorized to fill prescriptions and dispense to patients. If you give the medication to another medical provider, this is a distribution, and not a "prescription dispensing." If a pharmacy wants to send drugs to other medical providers, they may need to register as distributors;
- B) Section 195.070.5, RSMo states in material part that no practitioner may ever take possession of any portion of a patient's un-used controlled substance medication for any reason. Prescribers should never be taking possession of a patient's controlled substances.
- C) Practitioners may not prescribe controlled substances to themselves or self-administer controlled substances.
- D) The DEA has two exceptions at this time. Pharmacies can send prescriptions to doctor's offices for injectable buprenorphine and also Spravato™. Those are the only two exceptions at this time.

Dispensing Drugs For Infusion—The Pharmacy's Role

At the bureau's website under the link to publications, the bureau has an educational guideline that instructs how to obtain controlled substances for infusion, and what roles and records the prescriber and pharmacy must have.

Physicians who store controlled substances in their offices for administration must obtain those controlled substances from another registrant via the required transfer forms and not by solely issuing prescriptions to be dispensed by retail pharmacies. In obtaining compounded controlled substance medications for office or clinic administration, physicians and pharmacies are to meet the following requirements:

OPTION ONE—The patient picks up their own prescription from the pharmacy:

1. The physician writes a controlled substance prescription for the compounded medication;
2. The compounding pharmacy may prepare the prescription and dispense it to the patient as a properly labeled patient-specific prescription. The pharmacy must be in compliance with Missouri Board of Pharmacy compounding regulations;
3. The compounding pharmacy is registered as a retail pharmacy so the medications must be dispensed to a patient and not sent to the physician;
4. The patient picks up their medication and takes it to their physician's office for administration;
5. The physician documents the prescription and administration in the patient's chart and then destroys any unwanted remainder;
6. This option does not require the pharmacy to be registered as a distributor and it does not require a transfer record of controlled substances between the pharmacy and the registered physician;
7. The prescription was issued to the patient, was picked up by the patient and the doctor did not store or stock the controlled substances in their office.

OPTION TWO—Pharmacies send the compounded medications to the physician's office:

1. The physician writes a controlled substance prescription for the compounded medication;
2. The compounding pharmacy may prepare the prescription as a properly labeled patient-specific prescription. The pharmacy must be in compliance with Missouri Board of Pharmacy compounding regulations;
3. The pharmacy will not dispense the prescription to the patient but may send it directly to the prescribing physician for office administration;
4. The compounding pharmacy **must be registered with BNDD and DEA as a distributor** since controlled substances will be sent to other registered practitioners and not just dispensed to patients as a retail pharmacy;
5. If the medications are sent through the U.S. Postal Service, or private delivery service or common carrier, the medications should be packaged in non-descript packaging so that the contents are not disclosed. The packages should be signed for;

6. Physicians should write the prescriptions with all of the required information for a controlled substances prescription and be sure to include all of the information needed for the pharmacy to compound the medications;
7. The compounding pharmacy/distributor will be transferring the compounded controlled substances so the pharmacy will document controlled substances transferred out and the physician must maintain controlled substance receipt records for controlled substances entering their possession;
8. Upon receipt of controlled substances a registrant must document the date, drug name, strength, dosage form and quantity received. The record must also document the names, addresses and DEA numbers of the supplier and the receiver. A transfer form may be used that is available on the BNDD website at www.health.mo.gov/BNDD under the forms section. This form could be used for controlled substance compounds with drugs in Schedule III, IV, and V. Schedule II medications require a DEA Form 222 Official Order Form.

DEA Order Forms for Schedule II Medications:

1. The physician writes a Schedule II prescription with all of the information required;
2. The compounding pharmacy will be preparing the medication and transferring possession to the Physician;
3. The physician must submit a DEA Form 222 Official Order Form to the compounding pharmacy along with the prescription. DEA Order Forms may be obtained online at the DEA website www.deadiversion.usdoj.gov;
4. The top two copies of the DEA Order Form should be attached to the prescription;
5. The physician must retain their third copy of the DEA Order Form;

Prescriptions and Transfer Records for Controlled Substance Schedules III, IV, and V:

1. The physician writes a Schedule III—V prescription with all of the information required;
2. The compounding pharmacy will be preparing the medication and transferring possession to the Physician;
3. A transfer record must be maintained at the pharmacy and the physician's office. The record must document the drug name, strength, dosage form, and quantity. A transfer form is available at the BNDD website www.health.mo.gov/BNDD. The pharmacy must document the quantity transferred out and the date transferred out. The physician's records must document the quantity received and the date of receipt.

Record Keeping Requirements for Physicians:

1. All controlled substance prescriptions must be documented in the patient's chart;
2. All controlled substance administrations must be documented in the patient's chart;
3. When Schedule II medications are received, the third copy of the DEA Order Form must be completed that documents the quantity of drug received and the date of receipt;
4. DEA Order Forms must be filed separately from all other records and be maintained in chronological order.
5. Physicians must maintain records of all controlled substances received in the practice. DEA Order Forms will document the Schedule II medications. For medications in Schedules III, IV, and V, there must be a receipt record that documents the drug name, strength, dosage form, quantity received, the date received and the names, addresses and DEA numbers of both the supplier and the receiver. These receipt records should be filed separately from other records in the practice;
6. **Administration Log:** Physicians must maintain a log that is separate from patients' charts that documents the administration of controlled substances. The record must document the date, patient name, patient address, drug name, strength, form, quantity, and name or initials of person administering. There is an administration/dispensing form on the BNDD website at www.dhss.mo.gov/BNDD. This form may also be used to document the wastage of compounded medications;
7. If the practice is a multi-physician practice or clinic, each physician must maintain their own controlled substance records separately from the controlled substance records of the other practitioners. Each physician will have forms and documents with their own name and DEA number documented on them.

Record Keeping Requirements for Pharmacies:

1. The pharmacy must have separate registrations as a compounding pharmacy and a distributor;
2. The pharmacy will have two separate DEA numbers;
3. The prescriptions should be filed in the appropriate pharmacy file as normal;
4. The two types of DEA Order Forms should be separated; one file for the retail business and a separate file for the distribution registration.

Can a practitioner treat their own family?

In the state of Missouri, a prescriber cannot prescribe or dispense controlled substances to themselves. They are allowed to treat their own family members, provided that they treat them like all other patients and perform the required exams and maintain a patient chart.

Taking Back a Prescription You Dispensed

Section 195.070.4, RSMo authorizes a practitioner take back a controlled substance if they were the practitioner that originally dispensed the drug. If there is a dispensing error or there is another need to take back a prescription, you may do this if you document it thoroughly. Once the drugs leave the pharmacy they should be set aside for destruction and not re-dispensed to another patient. A practitioner may also witness a patient who wants to destroy their own prescription drugs if the patient no longer has a need for the drug.

Dispensing Prescriptions After the Prescriber has Died:

A prescription may be dispensed if it was legally written and issued in compliance with law, at the time the prescription was written. When a prescriber dies, this does not automatically terminate all of their prescriptions. The prescriptions and refills that were legally written are still valid and may be dispensed. It will be the patient's responsibility to find a new prescriber.

Testosterone in vials—Larger than Prescribed Amount:

Manufacturers stopped producing testosterone in smaller doses. Only limited sized vials are available and they are usually larger vials than what a physician would prescribe. This has created a challenge in the industry. Pharmacies are reminded that:

1. The largest quantity they can dispense is a 90-day supply;
2. The physician may change their prescription to adjust for that;
3. The physician may have to purchase and stock the testosterone in their office so they can administer as needed. This would eliminate prescribing.
4. A pharmacy can divide up a vial and re-package it into a smaller dose vial and label it, **IF** the pharmacy has a board permit as a sterile compounder.
5. A prescription cannot be written for a practitioner to obtain office stock for administering and dispensing.

SECURITY—PROTECTING YOUR PRACTICE

State and federal regulations require all registrants to have controls in place to prevent the diversion of controlled substances. It is not enough to just have policies and locks. The policies must be implemented and verified and the locks must be locked.

- Have a policy and procedure manual to train and guide employees. It is not enough to just have a policy and say, "obey all laws," but employees should know how to complete tasks and document records;
- Perform background checks on all employees before allowing them behind the pharmacy counter. Any person with a guilty plea for a controlled drug crime, regardless of the sentence or

punishment, cannot work with access to controlled drugs unless the employer has obtained a waiver. You should know the results of the criminal history before giving access to drugs.

- Pharmacies should always be able to review records to see what they have purchased and received;
- Limit who is allowed to purchase and check the drugs in upon receipt;
- Review the record keeping to verify you receive what you paid for;
- Have a system of checks and balances where all activities are reviewed by a second person;
- Do not allow employees to prepare prescriptions for themselves or relatives;
- Do not allow purses or coats in the pharmacy drug area;
- It is advised to have drinks in clear cups, or cups without lids. Many drugs have been stolen in styrofoam cups with lids;
- Search the trash for drugs before allowing it to be dumped;
- Perform random audits of selected drugs each month. Look at the balance of what your computer inventory says and then look to see if that is what is on the shelf;
- Frequently compare the drugs you are purchasing to see if they match the number of drugs your are dispensing;
- Be mindful of workers displaying signs of impairment or intoxication;
- Check computer records to see what prescriptions are return, removed, deleted or altered;
- Do not let the same person who purchases and orders drugs be the same person check them in and also pay the bills. Divide up the duties and require two people to sign or initial records;
- Arrange for a monthly self-inspection where records and activities are reviewed for compliance with policies and laws;
- Have signs in the customer area clearing stating that all prescription fraud is reported to law enforcement.

The PIC/Manager is required to supervise

The pharmacist-in-charge is required to supervise the other employees in the pharmacy. In recent times the practice of pharmacy has become very busy. Pharmacists get tied up dispensing and dealing with patients, doctors and insurers. At times, pharmacists may not be taking the time to supervise the staff. The recent trend in diversion from pharmacies is for technicians to steal entire stock bottles several times a week. There was a time when a person would steal a tablet or two or may create a false prescription, but recently there have been many incidents of employees just stealing entire bottles from the shelf. This went on for long periods without notice. The drugs were never audited and the finances were not noticed. Some pharmacies suffered losses of 30,000 to 78,000 doses. Amazingly the thieves were caught by others outside the pharmacy in illegal possession or DWIs and the pharmacy was usually the last to know.

What Constitutes a Legal & Legitimate Prescription

Federal and state regulations specify legitimate purposes for prescribing controlled substances:

- A prescription for a controlled substance is valid only if it is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice.

Certain criteria should be met:

- A) The prescriber must have proper controlled drug registrations.
- B) The patient must desire treatment for a legitimate illness or condition.
- C) A practitioner must establish a legitimate need through assessment, utilizing pertinent technical diagnostic modalities.

D) There must be reasonable correlations between the drugs prescribed and the patient's legitimate needs.

- The Intractable Pain Act, passed in 1995, provides guidelines for the treatment of chronic, intractable pain. This law was intended to clarify the parameters for treating chronic pain with controlled substances. The physician must document the diagnosis and treatment of chronic pain in the patient record and the use of controlled substances must be therapeutic in nature and manner utilized. Physicians may not prescribe or dispense controlled substances to a patient for chemical dependency unrelated to intractable pain or to a patient who the physician knows, or should know is using the medication in a non-therapeutic manner (unless they are approved and registered as a narcotic treatment program).

Practitioners may be subject to disciplinary action for non-therapeutic use of controlled substances, failing to keep accurate on-going treatment records, failing to keep complete and accurate controlled substance records, writing false or fictitious prescriptions, or prescribing controlled substances in a manner inconsistent with state or federal drug laws.

- Practitioners may not issue a prescription to obtain controlled substances for dispensing to patients. Practitioners can purchase controlled substance medications for stock from a drug distributor or pharmacy. A DEA form 222 must be used to obtain Schedule II controlled drugs. Each practitioner must maintain documentation as required under state and federal laws.
- Controlled drugs for a practitioner's personal treatment must be prescribed by another appropriate practitioner, under the basis of an established practitioner/patient relationship. Practitioners are prohibited by law from prescribing or dispensing controlled drugs for their personal use except in a true medical emergency.
- It is recommended that practitioners do not prescribe, dispense or administer controlled drugs to office staff or family members. If the physician does decide to treat family members or employees, the physician must do so under the auspices of a legitimate patient/physician relationship and in "good faith". This includes performing a proper evaluation, maintaining a chart, listing a diagnosis, plan of treatment and prognosis, and using the same documentation and care as with regular patients.
- For dentists, veterinarians, podiatrists and optometrists certified to use therapeutic pharmaceutical agents licensed by their respective professional boards, the prescribing, administering, dispensing or distribution of controlled substances is limited to the scope of their respective professional practice after establishment of a practitioner/patient relationship. If the practitioner does prescribe, dispense or administer to office staff or family members, these individuals must be treated in the same manner as regular patients. This includes maintaining a chart, listing a diagnosis, plan of treatment and prognosis, and using the same documentation and care as with regular patients.

Internet Prescribing

The Internet is primarily a communications tool that can be used to facilitate any type of business. The DEA issued a notice on April 27, 2001 in the Federal Register in reference to practitioners using the Internet as part of their business.

Some practitioners prescribe medications based on an on-line Questionnaire. Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice" ([21 CFR 1306.04\(a\)](#)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a practitioner to be acting in the usual course of professional practice, there must be a bona fide practitioner/patient relationship.

For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate practitioner/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A **physical examination** has been performed; and
- A legitimate clinical relationship exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Completing a questionnaire that is then reviewed by a practitioner hired by an Internet pharmacy can not be considered the basis for a practitioner/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a practitioner. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate practitioner/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone.

Prescriptions You Never Want to Fill

- A controlled substance prescription that a practitioner has written for themselves;
- A prescription that is not for a specific patient, but for stock in another practice;
- A prescription for methadone or other Schedule II drug, when it is for addiction detox or maintenance, for an adult;
- A prescription that does not have a prescriber's signature as required;

Never dispense without a prescription or legal authorization

Each year the bureau has several incidents where pharmacies dispense controlled drugs without a prescription. The pharmacy decides to go ahead and dispense drugs and get a prescription later, or give the patient some drugs now and subtract the quantity from the patient's next prescription. This is illegal drug distribution and bureau treats it as such.

Be Watchful for Professional Patients:

We humans are creatures of habit. We tend to operate out of convenience and use the pharmacies that closest to our doctor, home or work. We normally always use the same pharmacy. A sign of a professional patient is a person who patronizes 3 or more pharmacies routinely. It should also be a rare event for a patient to travel a great distance and bypass many other pharmacies to get a prescription from a pharmacy far from home.

What is the standard?

When it comes to compliance with laws and standards for security, the bureau has always noted the following in discussions with our registrants:

- The statutes and regulations are mandatory requirements and they set the minimum standard;
- Many professionals exceed the minimum standards required by the law;
- If a person has a controlled substances registration, they are expected to know the laws so they can comply;
- If a person has a position of a supervisor, they are expected to supervise;
- The bureau understands that these drugs are "controlled" because people will divert them. We understand that at some point, you have to trust employees and have humans touch the drugs and

diversions may occur. What the bureau is looking for is that a registrant has implemented the standard policies, procedures, and tactics in this guideline to prevent and detect diversion. Although a diversion of drugs may occur, the bureau wants to see that the normal standards were being met, the method of diversion was not easy and the diversion did not continue for months undetected.

Reporting Losses/Thefts and Diversions of Controlled Substances

The Missouri laws do not match the federal DEA laws. There are definitions that are different and the reporting forms are different.

DEA Loss Reporting: If drug are diverted or stolen, those are to be reported to the DEA. This may be on their form or submitted electronically at their website www.deadiversion.usdoj.gov. The DEA determines that an “insignificant” or small amount of loss does not have to be reported, however the registrant should monitor for a series or pattern of small losses. The DEA does not define or place a quantity on “insignificant.”

Missouri Reporting: Missouri defines “insignificant losses” and provides instructions on how to handle them. The state also provides specific reporting instructions for losses/thefts and mandatory reporting requirements. The state form is different and asks more questions. Loss report forms are available at the bureau’s website and a loss report form is included with this publication.

Insignificant Loss—Does not get reported to BNDD:

The drugs were not really “lost” and there was not crime or loss of accountability. This is when a compounding pharmacy has some liquid that sticks to the inside of a beaker or there is an amount of drug lost during a mixture or preparation. There was no theft or diversion. A tablet was dropped on the floor, stepped on and crushed and could not be picked up. When this happens, the drug was not truly “lost” because you know what happened to it. You must document this and what happened and it must be stapled to your annual inventory. Sometimes things accidentally happen to drugs and we must account for them. But the drugs were not stolen and we know what happened to them. These are “insignificant” losses and these get documented and attached to your annual inventory. You do not have to report if you receive a shortage of a tablet in a new stock bottle.

Lost or Stolen Controlled Substances:

These are cases where controlled substances were stolen, diverted or lost. This would include cases where drugs are missing and you are not sure where they went. These must be reported to the BNDD immediately upon discovery. The immediate notification may be by telephone, fax or email. You must submit a loss report form within 7 days. In Missouri, a loss/theft report is required when any amount is lost, stolen, diverted outside the law, or when the registrant does not know what happened to the missing drug. If you are conducting an internal audit and investigation and you need more time, you may contact the bureau and request more time to extend the 7 day reporting deadline.

Diversion: Missouri regulation requires the reporting of diversion. A diversion is when drugs leave their normal and legal channel and enter a path or circumstance not authorized by Chapter 195, RSMo. An example would be an employee that is doing something unlawful with controlled drugs, but not stealing them.

TECHNICIANS—LEADING SOURCE OF DIVERSION:

The BNDD collects loss, theft, and diversion reports from its 32,700 registrants. Consistently over the past few years, the leading source of theft has been by pharmacy technicians. With the implementation of automated dispensing systems and computers, and cells, the pharmacies are purchasing stock bottles in greater quantities and dumping them into cells. Technicians have been stealing entire stock bottles from the shelves, and sometimes several times a week. This sometimes has gone on for up to a year or more before being detected. The BNDD reminds registrants of Regulation 19 CSR 30-1.031(2), which states,

“Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations.” As controlled substance purchases and dispensings take place, the amount of security and supervision must be increased. The number one significant issue in these diversions has been lack of supervision. The following issues are for consideration by pharmacy managers:

- The BNDD has received technician theft reports ranging from 5,000 doses up to over 100,000 doses;
- Technicians are violating store policies by bringing coats, purses, and containers into the pharmacy. Although the pharmacy may have a policy against this, it is not being enforced;
- Technicians have been given individual access to computer systems where they can adjust drug counts and inventories without a supervisor;
- There should not be a document or record that says, “inventory adjustment.” That means something is wrong and unaccounted for and should be investigated immediately;
- There is not a periodic audit where the amount of doses purchased is compared against the number of doses dispensed;
- In many cases, the first clue that theft is taking place is not from the pharmacy management, but a technician may be arrested for DWI, or illegal possession, or illegal sales. In some cases a corporate office does a financial check and it reveals the pharmacy has purchased 100,000 doses but only dispensed 75,000 doses, so it’s the financial section that contacts the pharmacy manager and asks about the 25,000 missing doses.

Caution

The purpose of this information is to educate and inform the practitioner of the regulations and statutes pertaining to controlled substances and make recommendations to assist the practitioner in protecting their practice and patients from diversion, drug abuse and misuse. It is not the intent to reduce or deny the use of controlled substances where medically indicated. Nothing in this booklet shall be construed as authorizing or permitting any person to do any act that is not authorized or permitted under federal or state laws. In addition, none of the policy and information in this booklet may be construed as authorizing or permitting any person to do any act that is not authorized, or refuse to meet any requirements imposed under the regulations published in the most recent publication of the Code of State Regulations or the Revised Statutes of Missouri.

For additional information or questions, please email the BNDD at BNDD@health.mo.gov